## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE	) MDL NO. 1456
LITIGATION	) CIVIL ACTION: 01-CV-12257-PBS
	) Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	)
ALE CLASS ACTIONS	<i>)</i> )

# DEFENDANT PFIZER'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION

Zithromax injectable, the only Pfizer Inc. ("Pfizer") drug at issue, does not fit Plaintiffs' theory of this case. It would make no sense for Pfizer to create or promote large AWP spreads for Zithromax injectable because very few reimbursements for that product are based on AWP. Zithromax injectable is a hospital drug. More than 96% of Zithromax injectable sales are made to hospitals, and hospital reimbursement is not typically based on AWP.

Thus, it should come as no surprise that Plaintiffs have been unable to identify a single proposed class representative that made an AWP-based reimbursement for Zithromax, despite the fact that four years have passed since this case was originally filed. Plaintiffs concede that no Class 3 subclass may appropriately be certified as to Pfizer, and they do not even allege that any of the proposed Class 1 representatives is an adequate representative for claims against Pfizer. The lone Zithromax injectable transaction that purportedly provides standing to Class 2 representative Sheet Metal Workers National Health Fund ("SMW"), moreover, was clearly not based on AWP. None of the proposed class representatives have standing to pursue claims against Pfizer, so none of them may appropriately act as a class representative for claims against Pfizer. None of the proposed Pfizer subclasses should be certified.

### **ARGUMENT**

Plaintiffs bear the burden of offering a named representative who possesses standing to assert claims on behalf of the putative class. See Osediacz v. City of Cranston, 414 F.3d 136, 139 (1st Cir. 2005) (holding that plaintiff "bears the burden of pleading and proof on each step of the standing" inquiry); In re Eaton Vance Corp. Securities Litig., 219 F.R.D. 38, 43 (D. Mass. 2003) ("it is ultimately the named plaintiffs who bear the burden of establishing that class certification is appropriate"). Indeed, it is well established that unless plaintiffs offer sufficient evidence to "demonstrate the requisite case or controversy" between a proposed class representative and the defendant, "none may seek relief on behalf of himself or any other member of the class." Warth v. Seldin, 422 U.S. 490, 502 (1975) (citation and quotations omitted). Such is the case here. None of the proposed class representatives has standing to pursue AWP based claims against Pfizer either individually or as part of a class.

### I. PLAINTIFFS DO NOT SEEK TO CERTIFY CLASS 3 AGAINST PFIZER.

The proposed Class 3 representative, Pipefitters Local 537 Trust Funds, has not identified any reimbursements it made for Zithromax, AWP-based or otherwise. As such, it obviously lacks standing to pursue claims against Pfizer and just as obviously is unable to act as a class representative for a Class 3 Pfizer Subclass.

Recognizing that it is not appropriate to certify a class in the absence of an adequate class representative, Plaintiffs do not name Pfizer as a Class 3 defendant in their proposed class certification order. Consequently, no issues remain with respect to Class 3 claims as to Pfizer.

### II. THERE IS NO CLASS 1 REPRESENTATIVE IDENTIFIED FOR PFIZER.

Plaintiffs do include Pfizer as a Class 1 defendant, and ask the Court to certify a Class 1 Subclass for Pfizer, but there is no Class 1 representative identified for that Subclass. None of

the proposed Class 1 representatives were prescribed or made any AWP-based reimbursements for Zithromax injectable. Consequently, no Class 1 Subclass can be certified as to Pfizer.

### III. SMW IS NOT A MEMBER OF THE PROPOSED PFIZER CLASS 2 SUBCLASS.

As the basis for certifying Class 2 claims as to Pfizer, Plaintiffs' counsel have selected a single reimbursement made by proposed Class 2 Representative SMW. See Affidavit of Glenn Randle (hereinafter "Randle Aff.") Ex. 2 (attached to Plaintiffs' May 8, 2006 Brief in Support of Class Certification). That reimbursement, however, does not meet the proposed Class Definition for Class 2 claims as it is outside the time period for Class 2 claims and was not based on AWP. As such, SMW is not a member of the proposed class and thus cannot act as a class representative for a Class 2 Pfizer Subclass.

The proposed Class 2 Definition limits the proposed class to "[a]ll Third-Party Payors who made reimbursements for drugs purchased in Massachusetts, or who made reimbursements for drugs and have their principal place of business in Massachusetts, based on AWP for a Medicare Part B covered Subject Drug..." Plaintiffs' Proposed Order at 3. The stated Class Period for Class 2 claims is January 1, 1995 to January 1, 2005. *Id.* at 5. The single Pfizer reimbursement identified by SMW falls outside this class definition in three respects.

First, the reimbursement was made after the end of the class period. The documents produced by Plaintiffs reveal that the service date for the prescription underlying SMW's claim was See Randle Aff. Ex. 3(1) (SMWMASS 000045). That document also indicates that the "paid" date for the encounter was (Id.) Relying on either date, the transaction occurred well after January 1, 2005 and thus well outside of the stated Class Period.

Second, the SMW reimbursement was not based on AWP, so it does not fall within the Class 2 Definition. Beginning January 1, 2005, Medicare reimbursed for outpatient physician administered drugs based on Average Sales Price instead of AWP. Any Medicare Part B reimbursements that occurred on or after January 1, 2005, therefore, are, by statute, not based on AWP. See Expert Declaration of Steven J. Young ("Steve Young Decl.") 9 n. 15 (attached to the Track 2 Defendants' Joint Brief in Opposition to Class Certification).

Third, the reimbursement was not made under Medicare Part B. The documents produced by Plaintiffs indicate that the SMW reimbursement for Zithromax injectable covered services provided at Randle Aff. Ex 3(l). Hospital reimbursements were made under Medicare Part A, not Medicare Part B. And those reimbursements were not based on AWP at any point during the relevant time period. Steve Young Decl. ¶ 47.

SMW thus lacks standing to assert claims against Pfizer and is inadequate to act on behalf of the class it seeks to represent. Therefore, no Pfizer Subclass of Class 2 may be certified either.

### CONCLUSION

For all the foregoing reasons, Plaintiffs' Motion for Class Certification should be DENIED as to Pfizer.

This is not surprising given that Pfizer sales data reveals that Zithromax is sold almost exclusively to hospitals, with hospital sales comprising over 96% of all Zithromax sales (by units).

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Respectfully Submitted,

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